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510(K) Summary

JUN 2 2 2011

Apex PS Knee System

06 June, 2011

Submitter	OMNIlife science, Inc. 50 O'Connell Way E. Taunton MA 02718	**Contact**	Radhika Pondicherry Regulatory Affairs 774-226-1852 (508) 822-6030 (fax)

Preparation Date	06 June,2011
Device Name	Apex PS Knee System, PS-C Insert
Sizes	Sizes 1 thru 6 available in 6 thicknesses for each respective Insert size.
Common name/ Classification	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulatory Class	Class II per 21 CFR § 888.3565, 888.3560
Product Code	21 CFR Product Code-MBH , JWH
Legally Marketed Predicate Device(s)	Apex PS Knee System K102578
Device Description	The posterior stabilized system offers a femoral component and two tibial inserts (PS (K102578) and PS-C (subject device)) offering different levels of constraint. The PS-C Insert post is approximately 1 mm larger than the PS Insert (K102578). The slightly larger post is designed to produce more varus/valgus and internal/external rotational constraint

Indications for Use

The Apex Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
Rheumatoid arthritis;
Correction of functional deformity;
Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.

The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

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Predicate Device Comparison

	Apex PS Knee System PS-C Insert (subject device)	Apex PS Knee System, PS Insert (K12578)
Intended Use		
Priary and revision total knee replacement	Yes	Yes
Design		
Post Width	16 -21 mm depending on size	15 -20 mm depending on size
Varus/ Valgus Constraint	3 - 4°	No Varus/Valgus Constraint
Intenal/ External Rotation	11 - 17 °	14 - 20 °
Range Of Motion	Idntical to K102578	6° hyperextension and 132 ° flexion
Condyle Geometry and Contact Area	Identical geometry to K102578	Toroidal convex femoral surface and a toroidal concave insert surface with medial-lateral and anterior-postrior radii that increase wth component size
Tibia Baseplate Mating feature	Identical to K102578	Mates with two parallel dovetail rails on Tibia Baseplate.
Materials		
Ultra high molecular weight polyethylene	Identical to K102578	UHMWPE ASTM F648
PACKAGING AND STERILIZATION		
Sterilization	Identical to K102578	Ethylene oxide
SAL	Identical to K102578	10^{-6}
Packaging	Identical to K102578	Paper Board Box, Double Tyvek inner pouch

Non-Clinical Test Summary

The following tests were conducted:

- ROM evaluation per ASTM F2083-08, FDA " Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA"
- Tibio-Femoral Constraint per ASTM F2083-08, ASTM F1223-03

Clinical Test Summary

No clinical studies were performed.

Conclusions

In summary, the Apex PS Knee System PS-C Insert, in our opinion, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OMNIlife science, Inc.
% Ms. Radhika Pondicherry
Regulatory Affairs
50 O'Connell Way
East Taunton, Massachusetts 02718

JUN 2 2 2011

Re: K111184
Trade/Device Name: Apex PS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: June 6, 2011
Received: June 7, 2011

Dear Ms. Pondicherry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Pete D Rumm CLIN DEP DIR

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111184

Device Name: Apex PS Knee System

The Apex Knee [tm] System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;

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The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111184